Remarks

Reconsideration and allowance is requested.

This response is supported by the Declaration of Dr. William J. Rea, which is filed pursuant to 37 C.F.R. 1.132.

This response is accompanied by a request for extension of time. The Office Action cites an anonymous complaint filed against Dr. Rea with the Texas Medical Board. As explained below, this was not an adjudication or findings; these allegations are irrelevant, unfounded, and prejudicial and should not be considered. On August 27, 2010, the complaint In the Matter of the License of William J. Rea, M.D., was finally resolved by Mediated Agreed Order (a settlement agreement). Declaration of William J. Rea, ¶ 12–20.

This response is accompanied by a petition to make special in view of the advanced age of the named inventors.

Status of Claims

Claims 49–64, 67, and 70 are currently pending in the application.

No amendments to claims 49–64, 67, and 70 are being made.

Independent claim 70 is similar to pending claim 49 except that the preamble of claim 70 does not include the language "having an irregular cell cycle for T lymphocytes."

Examiner Suggested "Chemically Sensitive"; Objection to Piecemeal Examination

The piecemeal examination of this application is contrary to the policy of the Patent and Trademark Office. MPEP § 707.07(g).

The independent claims were amended 11 years ago to be directed to a method for treating "a chemically sensitive individual," *which was originally suggested by the Examiner in a telephone conference on March 16, 1999, and which had been in the claims ever since.* See the Amendment filed April 17, 1999, page 4.

For the first time in 11 years since then this language is used as the basis of yet another new rejection. This is after numerous rejections on various other piecemeal grounds, all of which Applicants have overcome, including by making two different appeals to the Board of Patent Appeals and Interferences.

Response to New Rejections Under 35 USC 112, First Paragraph (Enablement)

The non-final Office Action rejected the claims under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. This rejection is traversed.

Regarding Claims 49–64 and 67, the specification provides evidence of enablement for use in treating certain individuals: those who are chemically sensitive and have an irregular cell cycle for T lymphocytes. Regarding claim 70, the specification provides evidence of enablement for use in treating those who are chemically sensitive.

For enablement, all that is required is a sufficient disclosure to enable a person of skill in the art to practice the invention without undue experimentation.

A. Examiner Raises Irrelevant, Unfounded, and Prejudicial Allegations

In the Office Action dated March 18, 2010, on page 4, the Examiner states:

> … Barrett (2007) discloses a complaint filed against Inventor Rea filed with the Texas Medical Board which questions the validity of the diagnosis and treatment of chemical sensitivity as proffered by Inventor Rea. …

On August 27, 2010, the complaint In the Matter of the License of William J. Rea, M.D., was finally resolved by Mediated Agreed Order (a settlement agreement), a copy of which is attached as Exhibit B (8 pages) to Dr. Rea's Declaration. Declaration of William J. Rea, ¶ 14. See *Kloeris v. Stockdale*, 2010 WL 141305 (Tex. App. – Houston [1st Dist.] 2010, pet. Denied) (an agreed order from the Texas Medical Board is considered a settlement agreement, Tex. Occ. Code § 164.002(d); settlement agreements are not admissible to prove liability).

These allegations are irrelevant, unfounded, and prejudicial and should not be considered. Declaration of William J. Rea, ¶¶ 12–20.

To settle this matter, Dr. Rea agreed to change the Informed Consent documents used in his medical practice. Declaration of William J. Rea, ¶¶ 12–20, Exhibit B, In the Matter of the License of William J. Rea, Mediated Agreed Order, August 27, 2010, pages 3–6.

In addition, regarding the settlement Informed Consent documents, it is not required that a method, especially a medical treatment help in every case. "Considerations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled." MEPE 2164.05, citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) ("Testing for full safety and effectiveness of a prosthetic device is more properly left to the [FDA].").

In the Office Action dated March 18, 2010, on page 3–4, the Examiner also states:

> … In addition, regarding Inventor Rea and the use of the factor recited in the claims (aka ALF aka autogenous lymphocytic factor), Hall indicates that is unclear if ALF can actually be used to treat disease (see pages 3-4). …

These allegations by Hall (2009) are irrelevant, unfounded, and prejudicial and should not be considered. Declaration of William J. Rea, ¶¶ 21–25.

B. Chemical Sensitivity Refers to Symptoms, Not to Syndrome or Diseases

"Chemical Sensitivity" or "chemically sensitive individual" refers to symptoms. Declaration of William J. Rea, ¶¶ 27–31. The specification defines and uses "chemically sensitive" referring to symptoms. Declaration of William J. Rea, ¶¶ 32–35. The application and claims are *not* directed to "multiple chemical sensitivity" (aka "MCS"). Declaration of William J. Rea, ¶ 36. "Multiple chemical sensitivity" ("MCS") refers to a syndrome. Declaration of William J. Rea, ¶¶ 37–40. "Chemical sensitivity" symptoms are *not* "multiple chemical sensitivity" syndrome and should not be equated. Declaration of William J. Rea, ¶ 41. The claims are *not* directed to other diseases. Declaration of William J. Rea, ¶¶ 42–46.

C. Evidence of Treating an Irregular Cell Cycle for T Lymphocytes

The Office Action overstates the scope of the claimed invention, on page 4 (*emphasis added*):

> Regarding the use of the claimed method to regulate an abnormal lymphocytic cell cycle of continuously dividing *T and B lymphocytes* in a mammal wherein said method encompasses the in vivo treatment of humans, there is no evidence in the specification that such regulation has been achieved using the claimed method. Regarding Wands factors 1-3, the claimed method encompasses a method wherein according to the specification the abnormal lymphocytic cell cycle of continuously dividing *T and B lymphocytes in a mammal is normalized.*

Pending claim 49 is directed to "A method for treating a chemically sensitive individual having an irregular cell cycle for *T lymphocytes* …." Claim 70 is similar to pending Claim 49 *except* that the preamble does *not* include the language "having an irregular cell cycle for T lymphocytes."

In addition, the specification and claims do not require the irregular cell cycle for T lymphocytes be "*normalized*." Of course, this is a desired goal, but the claims are directed to "*treating*," which is illuminated by the specification:

> … treating the individual with a therapeutic amount of the ALF, and determining the individual's lymphocytic cell cycle to observe any regulatory effect on the lymphocytic cell cycle and subsets.

Specification, page 6, lines 16–18.

> … As treatment [with ALF] continued, in general, in about six weeks a more drastic shift *toward that of a normal profile was observed*.

Specification, page 14, lines 8–9 (*emphasis added*). The application and claims do not require complete regulation, but is *a basis* for regulation of the cell cycle. Declaration of William J. Rea, ¶¶ 47–49.

The normal cell cycle for both T and B lymphocytes was well known at the time the invention was made and the application was filed. Declaration of William J. Rea, ¶¶ 50–56. The specification evidences improvement in the cell cycle for T lymphocytes. Declaration of William J. Rea, ¶¶ 57–67. In addition, the claims do not require regulation of the cell cycle in patients suffering from autoimmune disease. Declaration of William J. Rea, ¶¶ 68–70.

The results obtained are too large to attribute to the placebo effect or any of the other therapies or treatments that had been used until that time in environmental medicine. Declaration of William J. Rea, ¶¶ 71–72. In addition, a theoretical explanation was offered in the specification. Declaration of William J. Rea, ¶¶ 73–74.

Under the Wands factors, no undue experimentation would be required. Preliminary evidence was provided at the time of filing the application of some highly successful treatments according to the claimed invention, in rate of response, degree of response, and frequency of response that could only be attributed to the new treatment with ALF. The specification provides a "cook book" example of the procedure for practicing the invention. The statements contained in the written description regarding the scope of the claimed invention as set forth in the presently pending claims are supported by the data presented. The level of the skill regarding the subject matter of the claimed invention is high. Based on the description in the specification and the above factors, there is no requirement for "undue experimentation." A person of skill in the art, based on the invention disclosure and with

good financial and time resources, could conduct additional testing and clinical trials using the invention to elucidate the cause-and-effect relationships involved. Declaration of William J. Rea, ¶¶ 75–79.

The enablement requirement of § 112 is satisfied when an application describes a claimed invention in a manner that permits one of ordinary skill in the art to practice it, without undue experimentation. MPEP § 2164.01. Thus, the mere fact that experimentation might be required is insufficient to support an enablement rejection. Further, even complex experimentation is not necessarily undue. MPEP § 2164.01.

Even if experimentation may be required in this case, it would not be undue. The question of enablement is one of predictability in view of what is known in the art. Consequently, the amount of guidance or direction needed to satisfy the enablement requirement is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. MPEP § 2164.03.

The specific question of whether experimentation is "undue" is determined based on the following eight Wands factors:

1. Breadth of the claims;
2. Nature of the invention;
3. State of the prior art;
4. Level of ordinary skill in the art;
5. Predictability of the art;
6. Amount of direction provided in the specification;
7. Any working examples; and
8. Quantity of experimentation needed relative to the disclosure.

MPEP § 2164.01(a), citing *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, a proper analysis of whether any experimentation is undue requires an analysis of *all* of the pertinent Wands factors. MPEP § 2164.01(a)(emphasis added). It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. *Id.*

The Applicants' preliminary work adequately establishes that the methods would have application beyond the specific work reported in the specification. A patent is not required to rise to the level of testing required for new drug approval or drug efficacy claims, but must be merely sufficient to teach to a person of ordinary skill in the art how to make and use the invention without undue experimentation. Based on the Applicants' specification, a person

of skill in the art would certainly be able to appreciate the invention and conduct any further routine studies that may be desirable, including regarding the cell cycles of any of the lymphocytes, determine an initial status of a lymphocytic cell cycle of the individual, make ALF according to the method, administer the ALF to the individual, and observe the effects on the cell cycle of the individual's lymphocytes, all according to the teaching of the specification and as claimed.

In view of the foregoing, Applicants respectfully submit that a person of ordinary skill in the art would be able to make and use the claimed invention, despite any experimentation that might be required. Applicants further submit that this conclusion is buttressed by the amount of knowledge in the state of the art as well as the predictability of the art, as well as the majority of Wands factors that weigh in favor of enablement. Therefore, the present application adequately enables the claimed invention.

Conclusion

Applicants requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 112. In fairness, Applicants have reasonably disclosed and claimed a useful, new, and non-obvious method over what had been done before. They deserve a patent for making their invention.

If a telephone interview will help conclude any matters of form or otherwise, the undersigned would sincerely appreciate a telephone conference and can normally be reached at the office number below.

Dated: September 20, 2010

Respectfully submitted,

/Todd E. Albanesi/

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